

## **REMARKS**

The Office Action dated October 2, 2003 has been carefully reviewed. Claims 1-33 are pending in this patent application. By this amendment, claims 1-20 have been canceled, claims 21-24, 26, 31, and 32 have been amended, and claims 34-44 have been added. Reconsideration of this application, as amended, is respectfully requested.

### **Allowable Subject Matter**

Claims 4, 13, 17, and 31 were indicated to contain allowable subject matter. Each of claims 4, 13, and 17 have been canceled. Claim 31 has not been amended because it is believed that the claim from which claim 31 depends is itself allowable.

### **Objection to Abstract**

The Abstract has been amended to shorten it in accord with Examiner's request.

### **Claim Objections**

Claims 8, 10, 14, and 19 were objected to due to an informality. Such claims have been canceled.

### **35 U.S.C. § 102 Rejection (Johnson)**

Claims 21 and 25 were rejected under 35 U.S.C. § 102 as being anticipated by Johnson et al. (U.S. Patent No. 5,609,642). Claim 21 was amended to more clearly define the invention. Reconsideration of claims 21 and 25 is respectfully requested.

#### Discussion Re: Patentability of Claim 21

##### *Applicants' Invention*

A problem associated with prior art devices in the area of joint replacement surgery is that once a trial reduction is complete, the trial tray (or base plate) must be removed in order to prepare the tibia for the insertion of the final tibial implant. Such preparation may involve forming a hole in the tibia with the aid of a tool guide such as a drill guide. However, the removal of the trial tray and the positioning of a drill guide onto the tibia is time consuming. Further, the process of removing the tray and subsequently locating the drill guide can introduce errors as the drill guide may not be located correctly on the tibia, thereby causing the hole formed in the tibia to be located incorrectly.

The present invention provides the solution of providing an assembly that includes a drill guide which can be positioned in relation to trial tray, wherein a drill can pass through a bore in the drill guide and the opening in the tray to allow the surgeon to cut a hole in the patient's tibia. Therefore, there is less chance of incorrectly positioning the drill guide as its position is dictated by the trial tray. Further, since the surgeon is no longer concerned with correctly positioning the

drill guide, the process is much less time consuming. Therefore, the present invention allows the surgeon to assess the stability and kinematics of an implant through the use of the evaluation member which receives rotating and non-rotating trial inserts, and then by simply removing the evaluation member from the tray and positioning a drill guide in relation to the tray, the surgeon can efficiently and accurately form a hole in the patient's tibia for receiving the final tibial implant.

*Applicants' Amended Claim 21*

Amended claim 21 reads as follows:

21. A prosthesis evaluation assembly, comprising:  
a tray configured to be supported on a proximal end of a resected tibia, said tray having an opening defined therein;  
an evaluation member having (i) a lower portion configured to be received within said opening, and (ii) an upper portion configured to support a trial insert thereon, said evaluation member preventing advancement of a tool through said opening of said tray when said lower portion of said evaluation member is received within said opening; and  
a tool guide having a bore defined therein, said bore of said tool guide being aligned with said opening of said tray so that a tool may be advanced through said bore of said tool guide and said opening of said tray to cut a hole in said proximal end of said resected tibia when said evaluation member is spaced apart from said tray.

Johnson teaches a tibial trial prosthesis and bone preparation system.

However, Johnson's system does not disclose an evaluation member and a tool guide that each cooperates with the tray as particularly claimed in claim 21. For instance, while Johnson's tray 11 does have an opening defined therein (see, e.g., V-shaped slot 20 of Fig. 1), Johnson does not disclose "an evaluation member having (i) a lower portion configured to be received within said opening, and (ii) an upper portion configured to support a trial insert thereon" as required

by amended claim 21. Nor does it have “a tool guide having a bore defined therein, said bore of said tool guide being aligned with said opening of said tray so that a tool may be advanced through said bore of said tool guide and said opening of said tray to cut a hole in said proximal end of said resected tibia when said evaluation member is spaced apart from said tray” as required by amended claim 21. Note that Johnson's trial insert 13 cannot meet the “evaluation member” element of amended 21 since it does not possess “an upper portion configured to support a trial insert thereon”. Indeed, Johnson's trial insert 13 is not configured to support another trial insert thereon. Nor does Johnson's trial insert 13 possess a lower portion configured to be received in the V-shaped slot 20 of its tray 11.

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Johnson does not disclose each and every element of Applicants' amended claim 21, Johnson does not anticipate Applicants' amended claim 21.

#### Discussion Re: Patentability of Claim 25

Claim 25 depends directly from claim 21. As a result, claim 25 is allowable over Johnson for, at least, the reasons hereinbefore discussed with regard to claim 21.

### **35 U.S.C. § 102 Rejection (Collazo)**

Claims 8, 9, 11, 12, 14, 21, 25-29, and 32-33 were rejected under 35 U.S.C. § 102 as being anticipated by Collazo et al. (U.S. Patent No. 5,872,925). Claims 8, 9, 11, 12, and 14 have been canceled. Claims 21, 26, and 32 were amended to more clearly define the invention. Reconsideration of claims 21, 25-29, and 32-33 is respectfully requested.

#### Discussion Re: Patentability of Claim 21

Amended claim 21 recites, among other things, the following:

a tool guide having a bore defined therein, said bore of said tool guide being aligned with said opening of said tray so that a tool may be advanced through said bore of said tool guide and said opening of said tray to cut a hole in said proximal end of said resected tibia when said evaluation member is spaced apart from said tray.

Collazo teaches a knee implant system. However, Collazo does not disclose “a tool guide having a bore defined therein, said bore of said tool guide being aligned with said opening of said tray so that a tool may be advanced through said bore of said tool guide and said opening of said tray to cut a hole in said proximal end of said resected tibia. Indeed, Collazo never discloses an opening in its tibial trial baseplate 15 ever being aligned with any bore of a tool guide (e.g. a drill guide). As can be seen in Collazo’s Figs. 1-4, there does not exist any openings in the tibial trial baseplate 15 that are configured to receive a tool that is guided by a tool guide (e.g. a drill guide).

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim.

Since Collazo does not disclose each and every element of Applicants' amended claim 21, Collazo does not anticipate Applicants' amended claim 21.

Discussion Re: Patentability of Claim 25

Claim 25 depends directly from claim 21. As a result, claim 25 is allowable over Collazo for, at least, the reasons hereinbefore discussed with regard to claim 25.

Discussion Re: Patentability of Claim 26

The discussion relating to the patentability of amended claim 21 is relevant to the patentability of amended claim 26. As a result, amended claim 26 is allowable over Collazo.

Discussion Re: Patentability of Claims 26-29 and 32-33

Each of claims 27-29 and 32-33 depends directly or indirectly from claim 26. As a result, each of claims 27-29 and 32-33 is allowable over Collazo for, at least, the reasons hereinbefore discussed with regard to claim 26.

**35 U.S.C. § 103 Rejection (Collazo/McCue)**

Claims 1-3, 5-7, 15-16, 18, 20, 22, 23, 24, and 30 were rejected under 35 U.S.C. § 103 as being unpatentable over Collazo et al. (U.S. Patent No. 5,872,925) in view of McCue et al. (U.S. Patent No. 5,733,290). Claims 1-3, 5-7, 15-16, 18, and 20 have been canceled. Claims 22, 23, and 24 were amended to

more clearly define the invention. Reconsideration of claims 22, 23, 24, and 30 is respectfully requested.

Discussion Re: Patentability of Claims 22-24

Each of claims 22-24 depends directly from amended claim 21. As a result, each of claims 22-24 is allowable for, at least, the reasons hereinbefore discussed with regard to amended claim 21.

Discussion Re: Patentability of Claim 30

Claim 30 depends directly from amended claim 26. As a result, claim 30 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 26.

**35 U.S.C. § 103 Rejection (Collazo/Lackey)**

Claim 10 was rejected under 35 U.S.C. § 103 as being unpatentable over Collazo and Lackey. Claim 10 has been canceled.

**35 U.S.C. § 103 Rejection (Collazo/McCue/Lackey)**

Claim 19 was rejected under 35 U.S.C. § 103 as being unpatentable over Collazo, McCue, and Lackey. Claim 19 has been canceled.

### **Newly Added Claims 34-44**

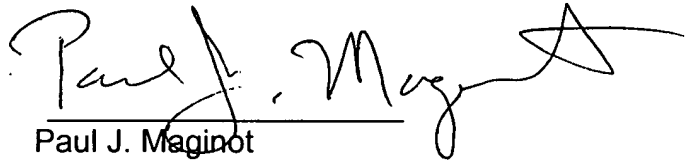
Newly added claims 34-44 recite novel and nonobvious limitations. Thus, each of claims 34-44 is allowable over the cited art.

### **Conclusion**

In view of the foregoing amendments and remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby solicited.

Respectfully submitted,

MAGINOT, MOORE & BECK

A handwritten signature in cursive script, appearing to read "Paul J. Maginot", with a large, stylized flourish at the end.

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